## Exhibit 16

## **DEA Update Notes**

Mark Caverly
Chief – Liaison and Policy Section
Office of Diversion Control

James (Jim) Crawford
Special Assistant to the Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

Crawford: How many of you represent manufacturers?

From those hands, how many different logos are used overseas?

Caverly: When addressed, stand up, tell us who you are and who you represent, so we can get you on film.

Crawford: Our labs have a heck of a time getting rid of our own stuff. We've got the same problems as you guys.

Caverly: Some questions are out of our areas of expertise. Can you believe that?

Question: I was told in May that the Chemical Handlers manual would be approved in the summer, but it is still not out.

Caverly: It is next in queue and circulating in within DEA. There is a weekly meeting making sure that it is consistent. Pharmacists are in Department of Justice now. We hope to get the Chemical Handlers Manual out as soon as we can.

Question: During the distributor breakout session. Suspicious Order Monitoring was certainly a hot bed of discussion. Are there any plans for DEA to publicize information to implement. SOM incorporate algorithms where products are more likely to be diverted.

Crawford: Whatever we put out will be outdated by the time we put it out. You're looking at a number. Tell me how much that we can't exceed. DEA can't do that. It's part of your due diligence...knowing your customer.

Question: What does DEA expect?

Caverly: Previously, DEA sat down with National Drug Association with an Algorithm. DEA standpoint – You know your customers better then we do. DEA stepped away from providing guidelines. It is not going to happen.

Question: Is there any update Hydrocodone might be moving from a CIII to a CII?

Caverly: "FDA is resisting that. I don't think there is any traction to the issue. Unintended consequence. FDA looking to withdraw from the market items that contain acetaminophen. If FDA removes combination products – Hydrocodone will be scheduled as a II. When it is mixed with acetaminophen, it becomes a CIII. DEA is watching from the sidelines. We don't have a horse in that race."

Question: E Prescription Rule.

Formerly accepted it. Rule is under review. Something DEA is working on since 1999. Have a rule from 1994. Office Management and Budget clock started ticking last week. Ahead of the game. Did own review. Several agencies reviewing rule. GSA volumes of Have taken a peek at it. Have something out probably February. 60 days implementation so probably early May.

Question: Re-exportation. A return was denied for clinical trials. Specifically seek DEA permission. Has DEA ever allowed to re-import something that was going to clinical trial?

We cannot waive statutory requirement.

List I and List II Importer? Exporter. New ruling talking whatever exporting not allowed to manifest. Is DEA is thinking about a threshold for methylamine?

Caverly: Former DEA employee is not head of the Bureau of Customs. In the future we will see more coordination of DEA with Customs. They are getting closer together.

Question: How are controlled bottles disposed of?

Crawford: No requirement. There was a case in New York where an employee responsible for cleaning the garbage took the empty bottles and filled them with aspirin and then sold them on the street. The empty bottles have value.

Question: Any updates on budget changes happening with DEA? Any educational activity or programs planned for the future?

Caverly: DEA graduated first Diversion Investigator class. First class in four to five years. DEA has 450 DI's nationwide. We reorganized, reorganized, reorganized. Emphasis on enforcement with tactical component. Special agents, DI, task force which includes local police officers. There are 21 DEA divisions. Focus more diversion on retail. Also involving physicians and pharmacies. Side by side emphasis on compliance. Enhanced compliance training with existing DI's for compliance education.

Buprenorphine will be visited by wholesale DEA.

Education – has not really been DEA's role. Demand reduction over all that has been funded for the past year. First year we have actually had a little money to spend. This has not been DEA's role in the past. 23 tactical diversion, 5 more planned.

Crawford: I'm the oldest guy around. Needed to recognize about half the dead suffered as a result of legitimate pharmaceuticals...has been that way for 35 years. Paying, intelligence, agents....The cost of the ticket on the wall has gone up.

Is DEA close to finalizing role on Destruction issues?

Caverly: Destruction issue is one of five. Waiting for Congress. Need additional Statutory Authority. Intended to signal DEA to do something, but realized we lacked the statutory authority to make the changes we needed to make. Combination of 2 bills around CSA to give us the tools. Nothing is expected to happen real soon.

Crawford: What's the cost? All of these Healthcare changes. How much does it cost? Competing interests. Cost customer way too much. Issues in upper echelon (of government). Everyone (Congress) is busy on Healthcare reform, and this activity is going on in the background.

Question: In regard to SOM. What is a company's responsibility for monitoring change with respect to controlled substances?

Know your customers. All sales going to a central location of that individual. Don't expect you to have a crystal ball. Use the best tools and information to make responsible business decisions.

CVS – As a whole sale distributor selling to distributor. They have the responsibility to know their customers. DEA is Monday morning quarterbacking. Should know you customers. It's the Mom and Pop stores buying 50% of their business as controlled substance. Cut them off! Distributing – Have responsibility to know your customer.

Question: 2010 Quota Grants. Asking for advance notice to give additional time. Quota requests have been able to be amended.

Caverly: "Quotas...Not my favorite subject. Quota section frowns on me when they hear me say it. One year Michael Morley took his remaining 2 weeks of vacation before he was due to lose them. Manufacturers were aghast that one person was taking vacation would affect the entire quota system. I think we could do a better job. We do the best under the circumstances. I don't have a good answer for you. I could sing and dance a little more if you would like."

Crawford: Did you adjust your assessment of need? You are in the business to make money. We are concerned with the necessary needs of the medical industry and no more. Michael Morley is one of the nicest guys in the world. He does the best he can. I don't know anyone that's been put out of business by not receiving quota. I've heard

rumblings of shortages. I've never been able to track shortages to lack of quota. You need to destroy your 5 mg Oxy tables because of manufacturing problems. Industry cries foul that DEA held back the Quota. We heard with Oxy that DEA held back the Quota. What happens is that a company will run out a particular sku, like they will have 10 mg tables available but not any 5 mg...cut the pills in half.

Question: Is it still required to use code K for ARCOS?

Caverly: I can ask Alan Drumheller. I don't know the answer to it.

Question: I have recognized an upswing in pain management clinics. What is DEA doing about the pain Management Community?

Caverly: Issue has not completely gone away. There is a better communication with the pain community. DEA sat down with pain community to provide guidelines and posted them on the website. They were promptly taken down after being posted. Many were outraged and there were some bitter feelings. We are communicating. The DEA felt the guidelines went outside DEA's responsibility. The medical community recognized that the relationship is better. The Agency is seeing pain clinics pop up. Florida...If you are going to do something illegal you do it in Florida...There are places where everyone pays the same amount per prescription.

We're aware and focusing on it. See it as illegal and not legitimate.

Question: Any recent developments with respect to pain management practitioners?

The State of Ohio Board of Pharmacy has a Suspicious Order Monitoring System and now they are telling pharmacies that they are out of luck. They are telling pharmacies that," You're not going to fill something that someone drove down to Florida to fill."

People in Kentucky are flying down to Florida and ask that their prescriptions from home be filled. States will stop it.

Crawford: It takes time to work a case. We may always take a ticket off the wall. Good people need pain treatment. My wife suffers from rheumatoid arthritis, and her doctor has a pain plan.

There is something wrong with an operation where everyone pays the same price for whatever pills.

Caverly: There are people in the pain community that do no like us. We've made it a point to reach out to them. They did actually invite us to their conferences. This relationship is new. It is better. I am attending one of their conferences in New York.